REMARKS

Claim 32 is amended in accordance with the discussions had during the June 21, 2005 interview. Applicants were told that this would address the prior art rejection and eliminate it, so no further remarks will be address thereto.

With respect to the Examiner Interview Summary, while it is correct it is incomplete. At the end of the interview, SPE Siew and Examiner Davis stated that they would confer with other Examiners, and advise applicants if the rejection would be maintained. Applicants have not heard anything thereafter. This response is filed on the assumption that nothing further will be forthcoming from the Examiner.

The single issue remaining in the case is the written description requirement. The Examiner has deemed claims 32, 34-37 and 40, but not claim 41, to lack adequate written description. Applicants have reviewed the Examiner's comments carefully, have studied the relevant law, and traverse.

The claimed subject matter is an immunoreactive portion of a protein. The "portion" is a portion of the molecule defined as that encoded by SEQ ID NO: 1. The protein this sequences encodes, i.e., NY-ESO-1, is well known. It encompasses many amino acid sequences corresponding to HLA binders.

The claims require that the claimed immunoreactive protein be processed, such that a peptide is produced, which stimulates a T cell response. The peptides of SEQ ID NO: 4, 5, and 6 are examples of this; however, the invention is not so limited.

Various, representative peptides consisting of amino acid sequences found in the NY-ESO-1 protein encoded by SEQ ID NO: 1, are set forth in the specification at page 26.

These are peptides which, according to known rules of MHC binding, would be expected to bind to particular HLA molecules. Page 25, Example 13, incorporates the source of such rules by reference. Additional references which set forth these rules are provided at Example 12, page 24.

It is uncontested that for a peptide to be one that is described in, e.g., claim 32, binding to an MHC molecule is not *per se*, sufficient. MHC binding does not guarantee that a particular peptide will provoke a T cell response; however, the methodologies by which one determines those which do stimulate T cells are described in the specification, and were used to determine that described SEQ ID NOS: 4, 5 and 6 constitute such peptides.

Peptides which are proven to be T cell stimulators and full within the scope of the claims of the invention are known. While this evidence has been dismissed by the Examiner, it is of record.

The Examiner has maintained a written description rejection of the claims, arguing that the decision University of California v. Eli Lilly & Co., 43 USPQ2d, 1398 (Fed. Cir. 1997) controls. According to the Examiner:

> "The specification does not disclose structural features common to the members of the genus of immunoreactive portions, which features constitute a substantial portion of the genus."

This, however, is not true. All claimed molecules share the structural requirement of having to have an amino aid sequence encoded by SEQ ID NO: 1.

In this respect, the Interim Written Description Guidelines, Example 14 in particular, are relevant.

Example 14 sets forth as a proposed claim:

> A protein having SEQ ID NO: 3 and variants thereof that are at least 95% identical to SEQ ID NO: 3 and catalyze the reaction of A→B.

The example discusses how making "variants" is conventional, as are processes for determining if activity is retained. Only a single species, i.e., SEQ ID NO: 3, is disclosed. Given the disclosure of an assay for determining if the catalytic activity is present, the guidelines conclude that written description is satisfied, even though only one, specific species is identified.

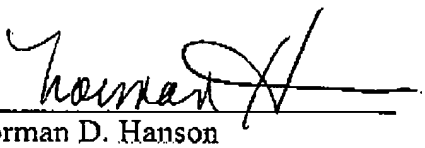
In the current application, three functional species are identified. No variation from a reference molecule is permitted. An assay is described, which the USPTO confirms is one that is usable. For convenience, a copy of the referenced Example 14 is attached.

With respect to the data submitted, the Examiner concludes that the specific peptides "are not disclosed in the specification." With all due respect, they are. These are peptides consisting of amino acid sequences encoded by SEQ ID NO: 1. This is clear from the specification. The Examiner is incorrect.

It is submitted that the Examiner's position in this application, as set forth in the final rejection of June 3, 2005, is improper, and should be withdrawn.

Allowance of this application is believed proper and is urged.

Respectfully submitted,

By 

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Attachment: Example 14

Example 14: Product by Function

Specification: The specification exemplifies a protein isolated from liver that catalyzes the reaction of **A** ⟶ **B.** The isolated protein was sequenced and was determined to have the sequence as set forth in SEQ ID NO: 3. The specification also contemplates but does not exemplify variants of the protein wherein the variant can have any or all of the following: substitutions, deletions, insertions and additions. The specification indicates that procedures for making proteins with substitutions, deletions, insertions and additions is routine in the art and provides an assay for detecting the catalytic activity of the protein.

Claim:

A protein having SEQ ID NO: 3 and variants thereof that are at least 95% identical to SEQ ID NO: 3 and catalyze the reaction of A ⟶ B.

Analysis:

A review of the full content of the specification indicates that a protein having SEQ ID NO: 3 or variants having 95% identity to SEQ ID NO: 3 and having catalytic activity are essential to the operation of the claimed invention. The procedures for making variants of SEQ ID NO: 3 are conventional in the art and an assay is described which will identify other proteins having the claimed catalytic activity. Moreover, procedures for making variants of SEQ ID NO: 3 which have 95% identity to SEQ ID NO: 3 and retain its activity are conventional in the art.

A review of the claim indicates that variants of SEQ ID NO: 3 include but are not limited to those variants of SEQ ID NO: 3 with substitutions, deletions, insertions and additions; but all variants must possess the specified catalytic activity and must have at least 95% identity to the SEQ ID NO: 3. Additionally, the claim is drawn to a protein which **comprises** SEQ ID NO: 3 or a variant thereof that has 95% identity to SEQ ID NO: 3. In other words, the protein claimed may be larger than SEQ ID NO: 3 or its variant with 95% identity to SEQ ID NO: 3. It should be noted that "having" is open language, equivalent to "comprising".

The claim has two different generic embodiments, the first being a protein which comprises SEQ ID NO: 3 and the second being variants of SEQ ID NO: 3. There is a single species disclosed, that species being SEQ ID NO: 3.

A search of the prior art indicates that SEQ ID NO: 3 is novel and unobvious.

There is actual reduction to practice of the single disclosed species. The specification indicates that the genus of proteins that must be variants of SEQ ID NO: 3 does not have substantial variation since all of the variants must possess the specified catalytic activity and must have at least 95% identity to the reference sequence, SEQ ID NO: 3. The single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO: 3 which are capable of the specified catalytic activity. One of skill in the art would conclude that

applicant was in possession of the necessary common attributes possessed by the members of the genus.

Conclusion: The disclosure meets the requirements of 35 USC §112 first paragraph as providing adequate written description for the claimed invention.